



## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Establishment of the Discretionary Advisory Committee on Heritable Disorders in Newborns and Children and Notice of Meeting**

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice of establishment of the Discretionary Advisory Committee on Heritable Disorders in Newborns and Children and Notice of Meeting.

**AUTHORITY:** The Committee is governed by Public Health Service Act (PHS), 42 U.S.C. 217a: Advisory councils or committees as well as provisions of Public Law 92-463, as amended, (5 U.S.C. App. 2), which sets forth standards for the formation and use of advisory committees.

**SUMMARY:** The U. S. Department of Health and Human Services announces the establishment of the Discretionary Advisory Committee on Heritable Disorders in Newborns and Children. This notice also announces the Committee's first meeting.

**FOR FURTHER INFORMATION CONTACT:** Debi Sarkar, Health Resources and Services Administration, Maternal and Child Health Bureau; Telephone: 301-443-1080;  
Email: [dsarkar@hrsa.gov](mailto:dsarkar@hrsa.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background and Authority**

Under the Public Health Service Act (PHS), 42 U.S.C. 217a, the Secretary of Health and Human Services directed that the Discretionary Advisory Committee on Heritable Disorders in Newborns and Children (DACHDNC) shall be established within the Department of Health and

Human Services (HHS). To comply with the authorizing directive and guidelines under the Federal Advisory Committee Act (FACA), a charter was filed with the Committee Management Secretariat in the General Services Administration (GSA), the appropriate committees in the Senate and U.S. House of Representatives, and the Library of Congress to establish the Committee as a discretionary federal advisory committee.

The purpose of the Discretionary Advisory Committee on Heritable Disorders in Newborns and Children (DACHDNC) is to advise the Secretary of Health and Human Services about aspects of newborn and childhood screening and technical information for the development of policies and priorities that will enhance the ability of the State and local health agencies to provide for newborn and child screening, counseling and health care services for newborns and children having, or at risk for, heritable disorders. The DACHDNC will review and report regularly on newborn and childhood screening practices, recommend improvements for newborn and childhood screening programs, as well as fulfill the list of requirements stated in the original authorizing legislation.

## **II. Structure**

The Committee consists of fifteen (15) voting members, including the Chair. The members of the Committee were appointed by the Secretary. Membership is composed of the Chair, Special Government Employees (SGEs) and federal ex-officio members. Federal ex-officio members include the Administrator of the Health Resources and Services Administration; the Directors of the Centers for Disease Control and Prevention; the National Institutes of Health; the Agency for Healthcare Research and Quality; and the Commissioner of the Food and Drug Administration – or their designees. The Chair and other members are (a) medical, technical, public health or scientific professionals with special expertise in the field of heritable disorders or in providing screening, counseling, testing, or specialty services for newborns and children at risk for

heritable disorders; (b) experts in ethics and heritable disorders who have worked and published material in the area of public health and genetic conditions; and (c) members from the public sector who have expertise, either professional or personal, about or concerning heritable disorders in order to achieve a fairly balanced membership.

The DACHDNC also includes nonvoting liaisons or representatives from Federal Agencies, public health constituencies, advocacy organizations and medical professional societies, as determined to be necessary by the Chair and/or the Designated Federal Official, to fulfill the duties of the DACHDNC. In addition, the DACHDNC is encouraged to work closely with other relevant HHS entities that focus on reviewing scientific evidence and making recommendations on clinical preventive services.

### **III. First Meeting of the DACHDNC**

**Dates and Times:** May 16, 2013, 10:00 a.m. to 2:00 p.m.

May 17, 2013, 10:00 a.m. to 2:00 p.m.

**Place:** Virtual via Webinar

**Status:** The meeting is open to the public. For more information on registration and webinar details, please visit the Committee's website:

<http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders>

**Purpose:** The Discretionary Advisory Committee on Heritable Disorders in Newborns and Children (Committee), as authorized by Public Health Service Act (PHS), 42 U.S.C. 217a: Advisory councils or committees, was established to advise the Secretary of the Department of Health and Human Services regarding the development of newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality

in newborns and children having, or at risk for, heritable disorders. The Committee's recommendations regarding additional conditions/inherited disorders for screening that have been adopted by the Secretary are included in the Recommended Uniform Screening Panel (RUSP) that constitutes part of the comprehensive guidelines supported by the Health Resources and Services Administration. Pursuant to section 2713 of the Public Health Service Act, codified at 42 U.S.C. 300gg-13, non-grandfathered health plans are required to cover screenings included in the HRSA-supported comprehensive guidelines without charging a co-payment, co-insurance, or deductible for plan years (i.e., policy years) beginning on or after the date that is one year from the Secretary's adoption of the condition for screening.

**Agenda:** The meeting will include: (1) a final report on the Pompe Condition Nomination for inclusion in the RUSP, and (2) updates on priority projects from the Committee's subcommittees on Laboratory Standards and Procedures, Follow-up and Treatment, and Education and Training.

The Committee is expected to vote on whether or not to recommend to the Secretary the addition of Pompe Disease to the Recommended Uniform Screening Panel (RUSP).

Certain proposed agenda items may be subject to change as necessary or appropriate. The agenda, webinar information, Committee Roster, Charter, presentations, and meeting materials are located on the Committee's website at

<http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders>

**Public Comments:** Members of the public can submit written comments and/or register to present oral comments during the public comment period of the meeting. All comments, whether oral or written, are part of the official Committee record and will be available for public inspection and copying. Advance registration is required to present oral comments or submit

written comments. Individuals who wish to make public comments are required to email Lisa Vasquez ([lvasquez@hrsa.gov](mailto:lvasquez@hrsa.gov)) by Tuesday, May 7, 2013. The public comment period is scheduled for the morning of May 17, 2013.

Written comments should identify the individual's name, address, email, telephone number, professional or business affiliation, type of expertise (i.e., parent, researcher, clinician, public health, etc.), and the topic/subject matter of comment. To ensure that all individuals who have registered to make oral comments can be accommodated, the allocated time may be limited. Individuals who are associated with groups or have similar interests may be requested to combine their comments and present them through a single representative. No audiovisual presentations are permitted.

**Contact Person:** Anyone interested in obtaining other relevant information should contact Debi Sarkar, Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18A-19, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857; telephone: (301)443-1080; email: [dsarkar@hrsa.gov](mailto:dsarkar@hrsa.gov). The logistical challenges of coordinating this meeting hindered an earlier publication of this meeting notice.

More information on the Committee is available at <http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders>.

Dated: April 25, 2013

Mary K. Wakefield,  
Administrator

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